K072809

APPENDIX G JUN 27 2008

510(k) Summary
Storz Medical AG
D-ACTOR Vibration Massager System

1. SPONSOR

Storz Medical AG
Lohstampfestr. 8
CH-8274 Tägerwilen
Switzerland

Contact Person: Pavel Novak
Telephone: +41-71-677 45 13
FAX: +41-71-677 45 05

Date Prepared: February 11, 2008

2. DEVICE NAME

Proprietary Name: D-ACTOR Vibration Massager System
Common/Usual Name: Therapeutic electric massager
Classification Name: Therapeutic electric massager

3. PREDICATE DEVICES

- Jet Therapy Therapeutic Massager subject of K002908
- G5/General Physiotherapy, Massager subject of K850581
- G5/General Physiotherapy Vibracare subject of K870939
- G5/General Physiotherapy, Fleximatic Massager subject of K852944

4. DEVICE DESCRIPTION

The D-ACTOR 200 is a vibrating percussion massage system that operates by compressed air to perform pulse activation therapy on target muscles and tissues. The D-ACTOR 200 unit features high-precision pneumatic components in its handpiece for pulse generation. The system consists of control unit, pneumatic handpiece and

pressurized air source, and includes an adjustable range of pressures and frequencies for use during treatment.

The D-ACTOR System is similar in function and purpose to other types of therapeutic massagers and vibrators. The design of the Storz Medical D-ACTOR is functionally similar to the design used by other legally marketed electric vibrators, except that the therapeutic pulses are pneumatically generated within the hand-held applicator.

5. INTENDED USE

The D-ACTOR Vibration Massage System is intended for the following:

- to relieve minor muscle aches and pains
- and for the temporary increase in local blood circulation

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The technological characteristics of the D-ACTOR device and the predicate devices are substantially equivalent in that they are all devices designed to provide mechanical stimulation to the skin for the relief of minor muscle aches and pains and to temporarily increase local blood circulation. The D-ACTOR functions by providing pressure pulses generated pneumatically. The method of delivery of mechanical energy to the patient is similar in both the proposed and predicate devices and also similar to other legally marketed therapeutic massagers and vibrators. Both the predicate D-ACTOR and the predicate devices deliver energy into the patient by applying a mechanical force (vibrations) to the surface of the skin. Both the D-ACTOR and the predicate device use various sized treatment heads to simulate the hand massage of tissues.

7. PERFORMANCE TESTING

Verification and validation testing was performed to demonstrate that the D-ACTOR components meet the design specifications. All tests required by the verification and validation plan have been completed and passed. Comparative performance testing demonstrated the D-ACTOR to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Storz Medical AG
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane
49 Plain Street
North Attleboro, Massachusetts

Re: K072809/S1
Trade/Device Name: D-ACTOR® 200 Vibration Massage System
Regulation Number: 21 CFR 890.5660
Regulatory Class: I
Product Code: ISA
Dated: May 16, 2008
Received: May 19, 2008

Dear Ms. NcNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K072809

Device Name: D-ACTOR® 200 Vibration Massage System

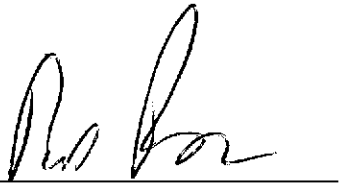
Indications for Use: "For relief of minor muscle aches and pains and for temporary increase in local blood circulation"

Prescription Use __XX_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)



(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K072809